

do not require retrofits to existing facilities or existing processes (e.g., those housing or adjacent to the new process); however, all facilities and processes must comply with the performance requirements in § 70.61. Licensees shall maintain the application of these criteria unless the analysis performed pursuant to § 70.62(c) demonstrates that a given item is not relied on for safety or does not require adherence to the specified criteria.

(1) *Quality standards and records.* The design must be developed and implemented in accordance with management measures, to provide adequate assurance that items relied on for safety will be available and reliable to perform their function when needed. Appropriate records of these items must be maintained by or under the control of the licensee throughout the life of the facility.

(2) *Natural phenomena hazards.* The design must provide for adequate protection against natural phenomena with consideration of the most severe documented historical events for the site.

(3) *Fire protection.* The design must provide for adequate protection against fires and explosions.

(4) *Environmental and dynamic effects.* The design must provide for adequate protection from environmental conditions and dynamic effects associated with normal operations, maintenance, testing, and postulated accidents that could lead to loss of safety functions.

(5) *Chemical protection.* The design must provide for adequate protection against chemical risks produced from licensed material, facility conditions which affect the safety of licensed material, and hazardous chemicals produced from licensed material.

(6) *Emergency capability.* The design must provide for emergency capability to maintain control of:

(i) Licensed material and hazardous chemicals produced from licensed material;

(ii) Evacuation of on-site personnel; and

(iii) Onsite emergency facilities and services that facilitate the use of available offsite services.

(7) *Utility services.* The design must provide for continued operation of essential utility services.

(8) *Inspection, testing, and maintenance.* The design of items relied on for safety must provide for adequate inspection, testing, and maintenance, to ensure their availability and reliability to perform their function when needed.

(9) *Criticality control.* The design must provide for criticality control including adherence to the double contingency principle.

(10) *Instrumentation and controls.* The design must provide for inclusion of instrumentation and control systems to monitor and control the behavior of items relied on for safety.

(b) Facility and system design and facility layout must be based on defense-in-depth practices.<sup>1</sup> The design must incorporate, to the extent practicable:

(1) Preference for the selection of engineered controls over administrative controls to increase overall system reliability; and

(2) Features that enhance safety by reducing challenges to items relied on for safety.

#### § 70.65 Additional content of applications.

(a) In addition to the contents required by § 70.22, each application must include a description of the applicant's safety program established under § 70.62.

(b) The integrated safety analysis summary must be submitted with the license or renewal application (and amendment application as necessary),

<sup>1</sup>As used in § 70.64, Requirements for new facilities or new processes at existing facilities, defense-in-depth practices means a design philosophy, applied from the outset and through completion of the design, that is based on providing successive levels of protection such that health and safety will not be wholly dependent upon any single element of the design, construction, maintenance, or operation of the facility. The net effect of incorporating defense-in-depth practices is a conservatively designed facility and system that will exhibit greater tolerance to failures and external challenges. The risk insights obtained through performance of the integrated safety analysis can be then used to supplement the final design by focusing attention on the prevention and mitigation of the higher-risk potential accidents.

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but shall not be incorporated in the license. However, changes to the integrated safety analysis summary shall meet the conditions of § 70.72. The integrated safety analysis summary must contain:

(1) A general description of the site with emphasis on those factors that could affect safety (*i.e.*, meteorology, seismology);

(2) A general description of the facility with emphasis on those areas that could affect safety, including an identification of the controlled area boundaries;

(3) A description of each process (defined as a single reasonably simple integrated unit operation within an overall production line) analyzed in the integrated safety analysis in sufficient detail to understand the theory of operation; and, for each process, the hazards that were identified in the integrated safety analysis pursuant to § 70.62(c)(1)(i)–(iii) and a general description of the types of accident sequences;

(4) Information that demonstrates the licensee's compliance with the performance requirements of § 70.61, including a description of the management measures; the requirements for criticality monitoring and alarms in § 70.24; and, if applicable, the requirements of § 70.64;

(5) A description of the team, qualifications, and the methods used to perform the integrated safety analysis;

(6) A list briefly describing each item relied on for safety which is identified pursuant to § 70.61(e) in sufficient detail to understand their functions in relation to the performance requirements of § 70.61;

(7) A description of the proposed quantitative standards used to assess the consequences to an individual from acute chemical exposure to licensed material or chemicals produced from licensed materials which are on-site, or expected to be on-site as described in § 70.61(b)(4) and (c)(4);

(8) A descriptive list that identifies all items relied on for safety that are the sole item preventing or mitigating an accident sequence that exceeds the performance requirements of § 70.61; and

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(9) A description of the definitions of unlikely, highly unlikely, and credible as used in the evaluations in the integrated safety analysis.

### § 70.66 Additional requirements for approval of license application.

(a) An application for a license from an applicant subject to subpart H will be approved if the Commission determines that the applicant has complied with the requirements of §§ 70.21, 70.22, 70.23, and 70.60 through 70.65.

(b) Submittals by existing licensees in accordance with § 70.62(c)(3)(i) will be approved if the Commission determines that:

(1) The integrated safety analysis approach is in accordance with the requirements of §§ 70.61, 70.62(c)(1), and 70.62(c)(2); and

(2) The schedule is in compliance with § 70.62(c)(3)(ii).

(c) Submittals by existing licensees in accordance with § 70.62(c)(3)(ii) will be approved if the Commission determines that:

(1) The requirements of § 70.65(b) are satisfied; and

(2) The performance requirements in § 70.61 (b), (c) and (d) are satisfied, based on the information in the ISA Summary, together with other information submitted to NRC or available to NRC at the licensee's site.

### § 70.72 Facility changes and change process.

(a) The licensee shall establish a configuration management system to evaluate, implement, and track each change to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel. This system must be documented in written procedures and must assure that the following are addressed prior to implementing any change:

(1) The technical basis for the change;

(2) Impact of the change on safety and health or control of licensed material;

(3) Modifications to existing operating procedures including any necessary training or retraining before operation;